PATENT

P-9565-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	SIEGEL, S.J.	Examiner:	FUBARA B.M.
Serial No.:	10/046,504	Group Art Unit:	1618
Filed:	October 19, 2001	Confirmation No.	3358
Title:	POLYMER-BASED SURGICALLY IMPLATABLE HALOPERIDOL DELIVERY SYSTEMS AND METHODS FOR THEIR PRODUCTION AND USE		

DECLARATION UNDER RULE 37 C.F.R. 1.132

Assistant Commissioner for Patents

Washington, DC 20231

I, DAVIS, Stanley (Bob), a citizen of the United Kingdom, residing at Nottingham, UK, hereby declare:

1. I am Emeritus Professor of Pharmaceutical Sciences at the University of Nottingham, Nottingham, UK. I was Professor of Pharmaceutical Sciences at Nottingham University from 1975 to 2003. I am also Chairman of Cosmas-Damian Ltd. a consulting company. I have a Bachelors degree in Pharmacy from London University and a Ph.D. in Colloid Science from the same institution; I also have a higher degree (D.Sc) from London University. My fields of expertise are pharmaceutical preformulation, controlled release systems, polymer matrices and polymer microspheres, transmucosal delivery of challenging drugs, nasal drug delivery, nose-to-brain drug delivery, drug targeting using colloidal carriers, biomedical applications of nanotechnology, gene delivery, the use of gamma scintigraphy for the evaluation of drug dosage forms, lipid vehicles for improved drug administration, in particular emulsion systems and vitamin E, absorption windows in the gastrointestinal tract, gastroretention and colonic targeting.

2. In addition, I was the principal investigator (PI) and senior scientist on the Cheng et al., reference and it was in my laboratory; and under my supervision that Dr. Cheng conducted the research as was described in the Cheng et al reference: "A poly (D, L-lactide-co-glycolide) microsphere depot system for delivery of haloperidol," in the Journal of Controlled Release 55 (1998) 203-212).

3. My Curriculum Vitae and list of publications are attached herewith as Appendix 1.

4. I have read the subject Application and have reviewed the patent prosecution history of the subject Application, including the Office Action of February 10, 2004, September 13, 2005, April 8, 2005, August 25, 2005 (advisory action), November 16, 2005, May 4, 2006, October 19, 2006, January 16, 2008 and September 3, 2008 and the references that served as basis for the Examiner's rejection of the claims.

5. The Subject Application claims:

> Claim 1: A surgically implantable drug delivery system, comprising (a) a biodegradable polymer or copolymer, wherein said biodegradable polymer or copolymer consists essentially of polylactide or lactide-co-glycolide copolymer; and (b) 20 to 40% haloperidol fabricated into an individual, surgically implantable implant via solvent casting and compression molding at a temperature and pressure which allows the haloperidol-polymer material to flow into a mold for the individual, surgically implantable implant which is surgically implanted underneath the skin of a patient, delivers steady state concentrations of haloperidol to the patient for 5 months or more and is removable from the patient in the event the patient exhibits unwanted side effects following implantation.
>
> Claim 4: A method of producing an individual, surgically implantable implant which is surgically implanted underneath the skin of a patient for delivery of steady state concentrations of haloperidol to the patient for 5 months or more comprising: (a) dissolving between about 20% and 40% haloperidol and a biodegradable polymer consisting essentially of polylactide or lactide-co-glycolide copolymer in acetone; (b) solvent casting the haloperidol and biodegradable polymer solution to produce a completely dry haloperidol-polymer material; and (c) molding under compression the dry haloperidol-polymer material at a temperature and pressure which allows the haloperidol-polymer material to flow into a mold for the individual, surgically implantable implant which is surgically implanted underneath the skin of a patient, delivers steady state concentrations of haloperidol to the patient for 5 months or more, and is removable following implantation into a patient in the event the patient exhibits unwanted side effects following implantation.

6. The biodegradable single unit implant disclosed and claimed in the subject application has been formulated with Polylactide-coglycolide (PLG). It releases the drug haloperidol over a

period of about 5 months (140 days). An initial slow release phase was followed by a more rapid release phase. Based on such release studies a 4 month supply of haloperidol from a 500 mg implant was proposed. The implant has good physical stability (See subject Application at page 3, paragraph 0024).

7. In the Office Action dated January 16, 2008 and the Final Office Action dated September 3, 2008; the Examiner rejected claims 1 and 3 as being obvious under 35 U.S.C. § 103(a), as being unpatentable over Cheng et al, "A poly(D,L-lactide-co-glycolide) microsphere depot system for delivery of haloperidol," in Journal of Controlled Release 55 (1998) 203-212. The Examiner alleged that Cheng et al., 1.) allegedly describes haloperidol-loaded biodegradable poly (D,L-lactide-co-glycolide) (PLG) microsphere (abstract), achieved a 10% haloperidol; and 2.) that Cheng et al., discloses that a drug content of haloperidol from 14.6 to 23.9%, can allegedly be loaded onto the PLG microspheres.

8. The Examiner is incorrect in his assertions and it would not have been obvious for a person skilled in the art to obtain Applicants' claimed invention based on Cheng et al. for the reasons set forth hereinafter.

9. The Cheng et al. study used dichloromethane (DCM) as the solvent and the maximum solubility of haloperidol in dichloromethane (DCM) is about 15mg/ml. With polymer present in the system this level drops to about 10 mg/ml. In addition, Cheng et al used a fixed concentration of 50 mg/ml of polymer and found that a loading of 5mg/ml was about the maximum they could obtain before the end product became unacceptable due to growth of crystals. In Cheng et al., the actual loadings were less than theoretical, no doubt due to the escape (partitioning) of some of the drug into the aqueous phase during the solvent evaporation stage. This has been reported by others including Suzuki and Price (J Pharm Sci. 1985 Jan;74(1):21-4.) The product produced by Cheng et al., was deemed unacceptable due to the formation of crystals of the drug that were found free in the final product. Some of these crystals could be removed by washing but under scanning electron microscope (SEM) it was seen that some crystals were still adhering to the surface of the microparticles. Such free crystals could give an unacceptable 'burst' of drug on administration.

10. Conversely, the formation of the implant as described in the subject application is different. There would be no possibility of forming free crystals since a one phase process was used. Therefore, modifying the microspheres described by Cheng et al., by incorporating 20-40% haloperidol as described in the subject application and using the fabrication method described by Cheng et al., would lead to an unacceptable product for the purpose of serving as a drug depot.

11. The maximum theoretical loading available to Cheng et al using dichloromethane (DCM) as the organic solvent and 50 mg of the polymer for fabrication was about 10% (calculated as mass of drug to mass of final microsphere product). Cheng et al restricted their attention to dichloromethane (DCM) as the organic solvent for drug and polymer, while the subject application uses Acetone as the organic solvent to dissolve the drug and polymer. It would have been unreasonable to expect that loadings of haloperidol from 20-40% could have been successful if one was still to use a process where the drug was dissolved in the polymer solution (as described in the subject application) and where one would obtain a microsphere system containing sufficient polymer to have an acceptable physical integrity and release profile for clinical application. Loading higher than 10% could well have been achieved by suspending solid drug in excess to the solubility of haloperidol in the polymer solution but this would not have been a sensible strategy to obtain small PLG loaded microspheres with a slow and reliable release rate and was not done in either by Cheng et al, or the subject Application.

12. It is my opinion that the results reported by Boisdron-Celle ("Preparation and characterization of 5-fluorouracil-loaded microparticles as biodegradable anticancer drug carriers". 1995 J. Pharm Pharmacol. Feb;47(2):108-14), would not teach a person skilled in the art that it would be possible to obtain similar loading levels for haloperidol when the drug was incorporated into a microsphere system by dissolving the drug in an organic solvent along with the polymer. This is because the two drugs are totally different. The high drug loadings reported by Boisdron-Celle et al were obtained using the water soluble drug 5-fluoruracil. This drug is insoluble in DCM. Hence the drug was loaded as a suspended solid and not by dissolving the drug in an organic solvent. Their paper describes how the particle size of the incorporated suspended drug affected the properties of the microspheres and the release of the drug. Cheng et al. cited Boisdron-Celle simply to give another example of actual drug loading being less than expected (even for a system where the drug was incorporated as insoluble particles). It should also be noted that the microspheres formed by Boisdron-Celle were an order of magnitude larger that those reported by Cheng et al.

13. Cheng et al. do not disclose implants with actual Haloperidol concentration between 20-40%. The highest drug concentration disclosed in the microsphere depots described by Cheng et al., is 3.07% (see Table II, pp. 208 of Cheng et al.), with 9.09% initial loading of Haloperidol. Nowhere in Cheng et al., is 20-40% Haloperidol mentioned or demonstrated, but rather for the system studied a theoretical 10% maximum concentration and an actual maximum haloperidol concentration of 2.78 ±0.20 were reported (See e.g. Table II, page 208).

14. Cheng et al., show a decrease in encapsulation efficiency with increasing initial Haloperidol concentration, while the implant system described in the present Application do not and cannot. As discussed above this is due to the fact that microsphere systems were prepared by a different method to the implant system. The skilled person would have appreciated this difference and would not have attempted to modify the microsphere depots disclosed by Cheng et al., by trying to double or quadruple the initial drug loading according to the subject Application.

15. Based on Cheng et al., it would be unreasonable to expect initial theoretical concentrations of Haloperidol higher than 10% using the system described in their studies, while the present Application gives Examples of final Haloperidol concentrations between 20-40%.

16. Due to saturation and subsequent crystallization of haloperidol in the system reported in Cheng et al.., an attempt to incorporate 20-40% haloperidol into the polylactide or lactide-co-glycolide copolymer, as claimed in the subject Application would not have been successful. Cheng et al fixed the PLG content at 50 mg/ml. Initial drug (haloperidol) loadings above 15% (7.5 mg/50 mg PLG, see e.g. page 208 first paragraph), yielded saturation of haloperidol, resulting in needle crystal larger than 20 μm. being formed in the final product.

17. Therefore, it is my opinion that Cheng et al. do not disclose an implant containing 20-40% Haloperidol, moreover, it would not have been obvious for one skilled in the art to increase haloperidol from 9.09% to 20-40% based on Cheng et al. for the reasons set forth hereinabove.

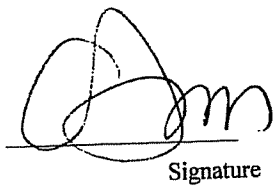
18. In addition, the Examiner has suggested that a microsphere system would be capable of removal in the event of adverse reactions and side effects. I disagree. A microsphere system, especially one with a mean particle size less than 10 micron as described by Chen el al. would comprise many tens or hundreds of thousands of particles depending upon the dose and mean particle size. The number of particles per unit weight can be calculated from the diameter of the particle assuming that the particles are spherical and monodispersed.

19. Microsphere systems are usually administered intramuscularly. An example of a marketed drug in a PLG microsphere system is Risperidone. This drug is practically insoluble in water but freely soluble in DCM. The extended-release microspheres formulation is a white to off-white, free-flowing powder that is available in dosage strengths of 12.5, 25, 37.5, or 50 mg Risperidone per vial. Risperidone is microencapsulated in 75:25 polylactide-co-glycolide at a concentration of 381 mg Risperidone per gram of microspheres. The microspheres are suspended in the diluent prior to injection.The microspheres are given by intramuscular injection (IM) into the buttock by a healthcare professional once every two

weeks. Injections are alternated between the two buttocks. It is hard to imagine recovery of this product from a patient. The implant system of the subject application is preferably implanted under the skin between the muscle and the dermis. It can be removed if needed.

The undersigned further declares that all statements made herein of his own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made, are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 27 Feb. 2009



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Curriculum Vitae Professor Stanley (Bob) Davis

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Professor SS (Bob) Davis obtained his Bachelors degree in Pharmacy from the School of Pharmacy at the University of London in 1964. He remained at the same University to study for a PhD in colloid science (1967). In 1966 he was appointed Assistant Lecturer in Pharmaceutics and then to Lecturer in 1967. He was awarded his Doctor of Science degree (higher doctorate) in 1982. In 1968 he was awarded a one year Fulbright Scholarship to undertake postdoctoral studies with Professor Takeru Higuchi at the University of Kansas, USA in the field of solution thermodynamics. In 1970 he moved to the University of Aston in Birmingham as Senior Lecturer and Head of the Pharmaceutics section. Here, he built up an active research group in drug delivery systems.

Professor Davis took the position of Lord Trent Professor of Pharmacy at Nottingham in 1975, where he ran a large research group, studying novel drug delivery systems. Topics of research have included drug targeting (with particular emphasis on colloidal carriers), transmucosal delivery, oral and parenteral systems for controlled release and product evaluation through gamma scintigraphy. He became an emeritus professor in 2003.

He has published over 750 papers and is co-editor of 7 books. He is the named inventor on numerous patents dealing with drug delivery. He is the Co-founder of three pharmaceutical companies; CDD (co-ordinated drug delivery) (now Vectura Ltd); Danbiosyst (UK) Ltd (sold to West Pharmaceutical Services and then to Archimedes) and Pharmaceutical Profiles Ltd. He has acted as a Consultant to various pharmaceutical companies and has worked as a visiting Scientist at Syntex, Allergan, and Alza. He has served on numerous Committees and Panels, to include those of the British and European Pharmacopoeias, the United Kingdom Medicines Commission, The Science & Engineering Research Council, UK.

Awards received include The Science Award (The British Pharmaceutical Conference, (1971), The Scheele Award (Swedish Pharmaceutical Association, 1985), The Maurice-Marie Janot Award (APGI, France, 1986) (The Harrison Memorial Medal, Royal Pharmaceutical Society, 2000), The Eurand Career Achievement Award for Outstanding Research in Oral Drug Delivery. The Controlled Release Society, 2003. The Host Madsen Medal (FIP) (2005).

He is a Fellow of the Royal Society of Chemistry, The Royal Pharmaceutical Society and the American Association of Pharmaceutical Sciences.

His non-scientific interests include skiing, sailing and art.

CHRONOLOGICAL LISTING

PUBLICATIONS - STANLEY S DAVIS

PhD (1967): The Effect of Emulsifier Concentration on the Rheological and Physical Properties of some Emulsion Systems (London University)

DSc (1981): The Physicochemical Properties of Pharmaceutical Systems (London University)

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